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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/805,813	02/26/97	MITSUHARA	I 085760-000

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EXAMINER

NELSON, A

ART UNIT	PAPER NUMBER
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1638

DATE MAILED:

03/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/805,813

Applicant(s)

MITSUHARA ET AL.

Examiner

Amy Nelson

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

Art Unit: 1638

DETAILED ACTION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1638.

Claim Rejections - 35 USC § 112

2. Claims 21, 22, 24-33, 35-41 remain rejected and new Claims 42-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record set forth in the Official actions mailed 12/16/98, 7/26/99, and 3/15/00. Applicant's arguments filed 2/2/01 have been fully considered but they are not persuasive.

Applicant asserts that the present invention is not directed to a new class of nucleic acids, but rather to the use of a known class of nucleic acids in a novel way, *i.e.* methods for using the nucleic acids to confer fungal resistance on plants, and to the transgenic plants. Therefore, Applicant asserts that holding of *Eli Lilly* is not applicable (response, p. 6). Because the nucleic acids are required to practice the claimed methods and to produce the claimed transgenic plants, the same standards for written description which would be applied to the nucleic acids are

Art Unit: 1638

applicable to the claimed methods/transgenic plants. The decision of the *Eli Lilly* case is indeed applicable to the instant invention because Applicant has not satisfactorily described the claimed genus of nucleic acids.

Applicant asserts that many anti-bacterial nucleic acids were known in the art at the time of filing of the instant application, and Applicant provides several references to support the assertion (response, p. 6). Examiner responds that most of the references are directed to peptide molecules and not to nucleic acid molecules, and hence do not provide a written description of nucleic acid molecules. The cited references only provide written description of cecropin nucleic acid molecules from the dipteran insects, *Drosophila* and *Ceratitis*. Whereas Applicant need not disclose all of the species encompassed by the claimed genus, Applicant must describe a representative number of species. Clearly Applicant has not provided an adequate written description of nucleic acid molecules encoding all anti-bacterial peptides from all species of dipteran insects, as broadly claimed.

3. Claims 21, 22, 24-33, 35-41 remain rejected and new Claims 42-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling only for claims limited to methods of enhancing fungal resistance with, and transgenic plants comprising, the sarcotoxin 1a gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is repeated for the reasons of record set forth in the Official actions

Art Unit: 1638

mailed 12/16/98, 7/26/99 and 3/15/00. Applicant's arguments filed 2/2/01 have been fully considered but they are not persuasive.

Applicant submits that anti-bacterial peptide sequences, other than sarcotoxin 1a, from Dipteran insects were known in the art at the time of Applicant's invention. Applicant cites several references that teach the availability of sarcotoxin 1b, 1c, and 1d; cecropin A, B, and D; and sapecin anti-bacterial peptides. Applicant also cites references that teach structural conservation among certain sarcotoxin and cecropin peptides. Based on the cited references, Applicant asserts that DNA molecules that encode the relatively short peptide sequences could be synthesized, and substituted for the sarcotoxin 1a gene of the instant invention (response, p. 7-9). Examiner responds that Applicant has not provided evidence to suggest that the structural relatedness corresponds to functional relatedness (*i.e.* antifungal activity) among the sarcotoxin and cecropin peptides, and hence it is unclear that one can be substituted for another. Applicant has provided no evidence to support structural or functional relatedness between sapecin and the other peptides. Also, the few peptides from a couple Dipteran insects disclosed in the prior art are not representative of the broad scope of Dipteran anti-bacterial peptides, as broadly claimed. Moreover, Examiner reiterates that whereas Applicant demonstrates the availability of anti-bacterial peptides, Applicant does not demonstrate the availability of nucleic acid molecules encoding anti-bacterial peptides, especially those encoding anti-bacterial peptides which have an anti-fungal effect in transgenic plants. Undue trial and error experimentation would be required to screen through the vast number of degenerate nucleic acid molecules which encode the peptides

Art Unit: 1638

disclosed in the prior art to identify those which are actively expressed in transgenic plants, and which also have an anti-fungal effect. As stated by Applicant in the response filed 12/28/99 (p. 9-10), "it cannot be necessarily assumed that anti-fungal activity is inherent in any transgenic plants comprising an anti-bacterial gene from a Diptera insect ... In support, Applicants submit Florack *et al.*, Transgenic Research 4: 132-141 (1995). Florack *et al.* transformed tobacco with an anti-bacterial peptide, Cecropin B, but failed to confer resistance to pathogenic bacteria on the resulting transgenic plant. Thus, the fact that a peptide exhibits anti-bacterial activity *in vitro* does not allow one to reasonably conclude that transgenic plants comprising such a peptide would confer resistance to bacteria, let alone to fungi." Therefore, the rejection is maintained.

4. Claims 21-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At Claim 21, lines 6-7, the phrase "compared to the plant before transformation" is unclear because the plant did not exist prior to transformation, rather the plant was regenerated from a transformed plant cell. It is recommended that the phrase be changed to --compared to a corresponding untransformed plant--.

At Claim 25, line 3, "chitinasa" is misspelled and should be changed to --chitinase--.

Art Unit: 1638

At Claim 32, line 7, the phrase "compared to the plant before transformation" is indefinite because there is no recitation of "transformation" earlier in the claim. It is recommended that the phrase be changed to --compared to a corresponding untransformed plant--.

Claims 42-47 comprise improper Markush language. Appropriate correction is required.

At Claims 42-47, line 2, before "Diptera insect" --a-- should be inserted for proper antecedent basis.

At Claims 42, 43, 45, and 46, line 3, the term "homolog" is indefinite because it is a relative term and it is not known what is encompassed by the term. There are many different types of homologs. It is not known how homology is determined and what level of homology is required. Appropriate correction is required to clarify the metes and bounds of the claimed invention.

At Claims 42 and 45, line 3, the phrase "derived from" is indefinite. There are many different types of derivatives and hence it is not known what is encompassed by the claim. Appropriate correction is required to clarify the metes and bounds of the claimed invention.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1638

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 1638

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy J. Nelson whose telephone number is (703) 306-3218. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310. The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application, or if the examiner cannot be reached as indicated above, should be directed to the legal analyst, Yolanda Vines, whose telephone number is (703) 305-2365.

A handwritten signature in black ink that reads "Amy Nelson". The signature is written in a cursive, flowing style.

**AMY J. NELSON, PH.D
PRIMARY EXAMINER**

Amy J. Nelson, Ph.D.

March 7, 2001